REMARKS

Claims 16-27 are pending in the subject application. Claims 16-24 are allowed. Claims 25-27 are under examination. Applicants have amended the specification. Accordingly, upon entry of this Amendment, claims 16-27 are still pending and claims 25-27 still under examination.

In view of the arguments set forth below, applicants maintain that the Examiner's rejections made in the June 6, 2003 Final Office Action have been overcome, and respectfully request that the Examiner reconsider and withdraw same.

The Claimed Invention

This invention relates to the detection and/or quantification of the extracellular domain of the human neu gene product in the biological fluid of humans using monoclonal antibodies which are capable of binding to this protein. Specifically, this invention provides a monoclonal antibody which is capable of binding to the extracellular domain of the human neu gene product, said product being detectable in a biological fluid by its immunoreactivity with a monoclonal antibody produced by the hybridoma cell line OD-3, NB-3 or TA-1, or with an immunoreactive fragment thereof.

Rejections Under 35 U.S.C. §102(e)

The Examiner rejected claims 25-27 under 35 U.S.C. §102(e) as allegedly anticipated by Ring et al. (U.S. Patent No. 6,054,561; "Ring"). The Examiner also rejected claims 25-27 under Hudziak et al. (U.S. Patent Nos. 5,720,937 and 5,772,997; "Hudziak I" and "Hudziak II", respectively).

Briefly, claims 25-27 relate to a monoclonal antibody which is capable of binding to the extracellular domain of the human neu gene product, said product being detectable in a biological fluid by its immunoreactivity with a monoclonal antibody produced by the hybridoma cell line OD-3, NB-3 or TA-1, or with an immunoreactive fragment thereof.

Under 35 U.S.C. §102(e), and as stated in M.P.E.P. §2131.01, "[a] claim is anticipated only if *each and every element* as set forth in the claim is found, either expressly or inherently described, in a single prior art reference." (emphasis added). Hence, to anticipate the methods of claims 25-27, Ring, Hudziak I and Hudziak II would each have to teach each and every element thereof.

Ring, Hudziak I and Hudziak II fail to do this.

Ring teaches a breast cancer-specific antibody designated 520C9 that binds to an approximately 200kD protein identified as "c-erbB-2." Ring also teaches another antibody designated 113F1 which recognizes a number of

diffuse bands with approximate molecular weights of 40, 60, 100 and 200kD.

Ring does not teach the claimed invention, i.e., a monoclonal antibody which is capable of binding to the extracellular domain of the human neu gene product. According to page 6, lines 9-15 of the instant specification, the claimed monoclonal antibody binds to a specific neu gene product that has a molecular weight of about 97 to 115 kDa. Furthermore, Ring does not teach that the product is *detectable in a biological fluid* by its immunoreactivity with a monoclonal antibody produced by the hybridoma cell line OD-3, NB-3 or TA-1, or with an immunoreactive fragment thereof.

The applicants again respectfully disagree with the Examiner's assertion that the antigens disclosed in the Ring patent, i.e., those ranging from 40-200kDa, read on applicants' range. The only antigen that falls within the range stated on page 6 of the specification, i.e., about 97 to 115kDa, is a *diffuse* band with an approximate molecular weight of 100 kDa which is recognized by the 113F1 antibody. There is no teaching in Ring et al. that the 113F1 antibody binds to the extracellular domain of the human neu gene product, nor even the "200kDa protein identified as c-erbB-2" disclosed in Ring. Furthermore, nowhere in Ring is it disclosed that the diffuse 100 kDa band is the extracellular domain of the human neu gene product. Rather, as stated in column 27, lines 22-24 of Ring, the 100 kDa band is one of a number of bands which "are suspected to be one or more glycoproteins bearing the same or similar carbohydrates." Therefore, Ring

fails to teach each and every element of the rejected claims.

Hudziak I and II teaches a monoclonal antibody that specifically binds to the extracellular domain of the HER2 receptor, and an assay for detecting tumors by determining the extent of binding of the antibody to *tumor* cells.

Like Ring, Hudziak I and II do not teach that the product is detectable in a biological fluid by its immunoreactivity with a monoclonal antibody produced by the hybridoma cell line OD-3, NB-3 or TA-1, or with an immunoreactive fragment thereof. Also like Ring, Hudziak I and II do not teach that the product is detectable in a biological fluid at all. Therefore, Hudziak I and II each fail to teach each and every element of the rejected claims.

In view of the above remarks, applicants maintain that claims 25-27 satisfy the requirements of 35 U.S.C. §102(e).

If a telephone conference would be of assistance in advancing prosecution of the subject application, applicants' undersigned attorney invites the Examiner to telephone him at the number provided below.

No fee, other than the concurrently enclosed $770.00 which includes the fee under 37 C.F.R. §1.17(r) for a first submission under 37 C.F.R. §1.129(a), is deemed necessary in connection with the filing of this

Amendment. However, if any additional fee is required, authorization is hereby given to charge the amount of such fee to Deposit Account No. 03-3125.

Respectfully submitted,

I hereby certify that this correspondence is being deposited this date with the U.S. Postal Service with sufficient postage as first class mail in an envelope addressed to:
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